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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,431	07/27/2005	Lawrence G Lum	57734 US (11259)	2810
21874	7590	08/17/2007	EXAMINER	
EDWARDS ANGELL PALMER & DODGE LLP			BELYAVSKYI, MICHAIL A	
P.O. BOX 55874			ART UNIT	PAPER NUMBER
BOSTON, MA 02205			1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/520,431	LUM ET AL.
	Examiner	Art Unit
	Michail A. Belyavskyi	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 June 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-25 and 39-54 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 26-38 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 05 January 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

1. Claims 1-54 are pending.
2. Applicant's election with traverse of Group V, claims 26-38 the reply filed on 06/01/07 is acknowledged. Applicant traverse the Restriction Requirement on the grounds that the search of Groups I-III together would not constitute a serious search burden on the examiner and that search of the claims of Group I would provide useful information for the claims of Group II and Group III.

This is not found persuasive because as has been stated in the previous Office Action, the inventions listed as groups I –IX do not relate to a single general invention concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-25 and 39-54 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 26-38 read on a method for tracking cells in vivo at any desired location, comprising arming the isolated cells with bispecific antibody and reinfusing said armed and labeled cells into a patient are under consideration in the instant application.

3. The use of the trademarks has been noted in this application. For example, on pages 21 and 50 of the instant specification the trademark "Herceptin" has been used. Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. Claim 34 is objected to as being dependent on canceled claims 1 and 15

Appropriate correction is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6 Claim 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Dependent claim 33 recites “wherein trafficking and homing of the armed and labeled cell...”. There is insufficient antecedent basis for this limitation in the claims, since base Claim 26 does not recite “trafficking and homing of the armed and labeled cell”.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

9. Claims 26, 30, 31 and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Sen et al (IDS).

Sen et al., teach a method of tracking or targeting T cells *in vivo* to a desired location comprising isolating and purifying a cell from a subject, arming said isolated cells with bispecific antibody, wherein said bispecific antibody has a binding site specific for cellular antigen and binding site specific for a target antigen and reinfusing the armed cells back into the patient. (see entire document, Abstract, Material and Method in particular).

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The reference teaching anticipates the claimed invention.

10. Claims 26, 30, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,86,1156 or Trevor et al., (IDS)

US Patent 156 teaches a method of tracking or targeting T cells *in vivo* to a desired location comprising isolating and purifying a cell from a subject, arming said isolated cells with bispecific antibody, wherein said bispecific antibody has a binding site specific for cellular antigen and binding site specific for a target antigen and reinfusing the armed cells back into the patient. (see entire document columns 3, 4 , 9 -11 in particular).

Trevor et al., teach a method of tracking or targeting T cells *in vivo* to a desired location comprising isolating and purifying a cell from a subject, arming said isolated cells with bispecific antibody, wherein said bispecific antibody has a binding site specific for cellular antigen and binding site specific for a target antigen and reinfusing the armed cells back into the patient. (see entire document, Abstract, Material and Method in particular).

The references teaching anticipates the claimed invention.

11. Claims 26, 30, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/091398 (IDS).

WO'398 teaches a method of tracking or targeting cells *in vivo* to a desired location comprising isolating and purifying a cell from a subject, arming said isolated cells with bispecific antibody, wherein said bispecific antibody has a binding site specific for cellular antigen and binding site specific for a target antigen and reinfusing the armed cells back into the patient. (see entire document pages 5, 11 , 12, 16 and 17 in particular).

The reference teaching anticipates the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. Claims 26 –38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sen et al., or US Patent 5,86,1156 or Trevor et al., or WO 03/091398 or US Patent 7,074,405.

The teaching of Sen et al., or US Patent 5,86,1156 or Trevor et al., or WO 03/091398 has been discussed, *supra*.

The claimed invention differs from the reference teaching in that Sen et al., or US Patent 5,86,1156 or Trevor et al., or WO 03/091398 does not explicitly teach a method for tracking cells *in vivo* at a desired location, wherein said cells are bone marrow cells or stem cells, as recited in claims 27-29; or wherein tracking or homing labeled cells is detected by flow cytometry, as recited in claim 33, or wherein fluorescent label is green red etc, or wherein isolated cells is transformed with nucleic acid molecule encoding GFP or RFP, as recited in claims 34-38.

It would be conventional and within the skill of the art to: (i) identify the specific cell type that can be used for tracking *in vivo* at desired location, or (ii) determine the means for detecting the labeled cells for example by using well known flow cytometry technique or (iii) select a fluorescent label such as green, red, etc., GFP or RGP. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 26 –38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 7,074,405.

US Patent 405 teaches a method of using bi-specific antibody to deliver *in vivo* any biological moiety to any desired location (see entire document, columns 6 and 17 in particular). US Patent 405 teaches that said bispecific antibody should have a binding site that is specific for said biological moiety and binding site specific for a target antigen in any location in a patient (see columns 6 7 in particular). US Patent 405 teaches that said bispecific antibody can be labeled with fluorescent label to track or monitor the targeting of said delivery biological moiety to any desired location.

The claimed invention differs from the reference teaching in that US Patent ' 405 does not explicitly teach a method for tracking cells *in vivo* at a desired location, as recited in claims 26-38; or wherein tracking or homing labeled cells is detected by flow cytometry, as recited in

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claim 33, or wherein fluorescent label is green red etc, or wherein isolated cells is transformed with nucleic acid molecule encoding GFP or RFP, as recited in claims 34-38.

It would be obvious to one skill in the time the invention was made to substitute one type of targetable biological moiety with another type of targetable moiety, such as cells-specific antibody to deliver in vivo biological moiety to any desired location as taught by US Patent '405. Because both prior art references and the instant claims uses the same bi-specific antibody which has one binding specificity for targetable moiety and second antigenic binding site that specifically bind to targeted tissue, to deliver biological moiety to any desired location, it would have been obvious to one skilled in the art that substituting one type of targetable biological moiety with another type of targetable moiety would yield a predictable result of delivering said biological moiety to any desired location. (see *KSR International Co v Teleflex Inc.*, 550U.S.-, 82 USPQ2d 1385, 2007).

Claims 27- 38 are included because it would be conventional and within the skill of the art to: (i) identify the specific cell type that can be used for tracking in vivo at desired location, or (ii) determine the means for detecting the labeled cells for example by using well known flow cytometry technique or (iii) select a fluorescent label such as green, red, etc., GFP or RGP. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. No claim is allowed.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAIL BELYAVSKYI, PH.D.
PATENT EXAMINER

08/16/07